

**RESPONSE TO RESTRICTION REQUIREMENT**  
**U.S. Appln. No. 09/830,876**

**REMARKS**

On page 2 of the Office Action, the Examiner has issued a Restriction Requirement under 35 U.S.C. § 121 to one of the inventions of the following groups:

- Group I - Claims 1-15, drawn to an immunoassay to detect  $\alpha$ -amylase;
- Group II - Claims 16-18 and 20-22, drawn to a monoclonal and kit therefor; or
- Group III - Claim 19, drawn to a monoclonal antibody that binds to a conformational epitope on  $\alpha$ -amylase.

The Examiner contends that the inventions of Groups I-III do not relate to a single generic inventive concept, i.e., the Examiner contends that the assay of Group I does not require the monoclonal antibodies of Groups II and III, and the monoclonal antibodies of Groups II and II are not related, i.e., the antibody of Group II is required to only bind one amino acid sequence, whereas the antibody of Group III is required to bind all three sequences.

Applicant hereby elects the invention of Group I, i.e., Claims 1-15, drawn to an immunoassay to detect  $\alpha$ -amylase, with traverse.

Each of Claims 1-22 recite the special technical feature of an antibody that binds to an epitope of  $\alpha$ -amylase comprising one or more of the amino acid sequences IDRLVSIRTRGQIHS (SEQ ID NO:1), CRDDRPYADG (SEQ ID NO:2) and VNWNKVGGS (SEQ ID NO:3). As claimed, the present invention also extends to antibodies

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capable of binding one or more of these epitopes, which includes the subject matter of Claim 19, requiring binding to all three epitopes. In this respect, the skilled artisan would be aware that the requirement in Claim 19 for an antibody that binds to a conformational epitope is inherent in the requirement for binding to all three recited epitopes.

Applicant submits that the correct inquiry under PCT Rule 13.1 is not whether or not the assay of Group I requires the monoclonal antibodies of Groups II and III, or even whether or not the antibodies of Groups II and III are the same composition of matter. With respect, PCT Rule 13.2 clarifies PCT Rule 13.1 as follows:

Where a group of inventions is claimed in one and the same international application, the requirements of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. (Emphasis added)

Hence, it is necessary to inquire as to the contribution that one or more special technical features considered as a whole make over the prior art. It is also more than a single special technical feature may be relied upon to assert a contribution over the art. In the instant case, Applicant respectfully submits that there is no mention in the prior art of any immunizing epitopes of  $\alpha$ -amylase that comprise an amino acid sequence as recited in the claims of this application (i.e., SEQ ID NOs:1-3), or antibodies that specifically bind to


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those epitopes. As a consequence, Claims 1-22 define a special technical feature that make a contribution over the prior art when considered as a whole. This conclusion is supported by the fact that neither the International Searching Authority or the International Preliminary Examining Authority have alleged lack of unity of invention when applying the guidelines set forth in PCT Rule 13 to International Application No. PCT/AU99/00995. Similarly, the European Patent Office has not raised any allegation of lack of unity when applying the guidelines set forth in PCT Rule 13 to the corresponding allowed European application (European Application No. 99957719.0). A copy of the communication under Rule 51(4) EPC from the European Patent Office evidencing allowance of Claims 1-22 in the same application is affixed hereto as Exhibit I.

Accordingly, Applicant respectfully requests the Examiner to reconsider and to withdraw the restriction requirement.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

  
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